



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/768,762	01/29/2004	David V. Dunsmore	TAL:8460.0002	7042
152 7590 06/26/2007 CHERNOFF, VILHAUER, MCCLUNG & STENZEL 1600 ODS TOWER 601 SW SECOND AVENUE PORTLAND, OR 97204-3157			EXAMINER BALDWIN, GORDON	
			ART UNIT 1775	PAPER NUMBER
			MAIL DATE 06/26/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/768,762	Applicant(s) DUNSMORE ET AL.	
	Examiner Gordon R. Baldwin	Art Unit 1775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 and 27-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22, 27-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner's comments

Claim 23 is not included in the amendment of 3/29/2007. Claim 23 must be included in the next correspondence from the applicant. Consideration is cancelled for examination purposes.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 12-15, 18-22 and 27-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Uchiyama (U.S. Pat. No. 4,943,486).

Consider claims 1-5, Uchiyama teaches a coated article, with a metallic substrate containing cobalt group alloys and a outer layer of chromium nitride carbide with a metallic chromium layer placed between the substrate and the chromium nitride carbide layer. (Claim 1 and Col. 2 lines 45-65) Uchiyama also teaches that the inner layer of a metallic chromium layer can have a thickness less than the thickness of the outer layer containing chromium nitride carbide that can have a thickness of 3.0 μm (which is considered to be between 3 and 15 microns). (Col. 20, lines 13-22 and Table 1B) Additionally, since the coatings are taught to be put on a variety of utensils, and since Uchiyama teaches that the coating have "mar proof" qualities with good

adherence and good corrosion resistance, the coatings are also considered to be load bearing. (Col. 19, lines 25-40)

The recitation of the article being a medical device has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Consider claims 12-15, 18-22 and 27-29, Uchiyama teaches a coated article, with a metallic substrate containing cobalt group alloys with an outer layer made of chromium nitride carbide with a metallic chromium layer placed between the substrate and the chromium nitride carbide layer. (Claim 1 and Col. 2 lines 45-65) Uchiyama also teaches that the inner layer of a metallic chromium layer can have a thickness less than the thickness of the outer layer containing chromium nitride carbide that can have a thickness of 3.0 μm (which is considered to be between 3 and 15 microns). (Col. 20, lines 13-22 and Table 1B)

Since there does not seem to be a difference in the product given by the applicant and the product given by Uchiyama, then the process limitation of applicant's claims 12, 18-22, 27 and 29, beginning with the surface of the body being exposed to a gas including nitrogen is considered to be a product-by-process limitation and "[E]ven though product-by-process claims are limited by and defined by the process,

Art Unit: 1775

determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.”, (*In re Thorpe*, 227 USPQ 964,966). Once the Examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product (*In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983), MPEP 2113).

Claims 1, 5, 6, 10-12, 16-22 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Shetty (Pat. No. 5,308,412).

Consider claim 1, 10, 11, 16 and 17, Shetty teaches a method of surface hardening a cobalt-chromium based implant device. However, the term “cobalt-chromium material” is also taught to include a cobalt-chromium-molybdenum alloy, which includes ASTM F-75 and ASTM F-799. (Col. 3 lines 55-70) The implant device is taught to have a hardening process in which a layer of chromium nitride is attached to the surface of the metal alloy ((Col. 2 lines 64-70-Col. 3 lines 1-5 and Col. 7 lines 55-65). Additionally, the medical device of a cobalt-chromium material is placed in a nitrogen gas process with pressure applied at a temperature of 500-2400 degrees Fahrenheit to form a CrN layer as the surface layer. (Col. 5 lines 51-60 and claim 1)

Consider claim 5, Shetty teaches that the coating is for orthopedic implants (Col. 1 lines 5-12), which are considered to be load-bearing, therefore any surface that is placed on the implant is also considered to be load bearing. (Col. 8 lines 12-19)

Consider claim 6, Shetty teaches a first surface that can be made of a polymer, (which is considered to include polyethylene as shown by its use, Col. 7 lines 20-25) with a body composed of a cobalt-chromium based implant device with a hardening process in which a layer of chromium nitride is attached to the surface of the metal alloy (Col. 2 lines 64-70-Col. 3 lines 1-5 and Col. 7 lines 55-65).

Consider claims 12, 18, 19, 20, 21, 22 and 27, Since there does not seem to be a difference in the product given by the applicant and the product given by Shetty, then the process portions of applicants claims 12, 18-22, 27 and 29, beginning with the surface of the body being exposed to a gas including nitrogen is considered to be a product-by –process limitation and “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.”, (In re Thorpe, 227 USPQ 964,966). Once the Examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious different between

Art Unit: 1775

the claimed product and the prior art product (*In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983), MPEP 2113).

Claim 1-4 is rejected under 35 U.S.C. 102(b) as being anticipated by Kukino (U.S. Pat. No. 6,620,491).

Consider claim 1-4, Kukino teaches the CrN can be used as a hard coating layer with the outer most layer being a chromium nitride layer. Kukino also teaches an overlapping of the ranges for the film thickness where the hard coated layer can have a thickness of between 0.5 μ m-10 μ m. Kukino also states that the intermediate layer can be thinner than the outer hard coating layer by teaching that the intermediate layer can have a thickness of at most 1 μ m, which is thinner than the majority of the range taught for the outer most hard cover layer. (Col. 3 lines 20-28)

The recitation of the article being a medical device has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Claims 1, 12, 18-22 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Grab (U.S. Pat. No. 6,866,921).

Consider claims 1, 12, 18-22 and 27, Grab teaches a substrate made of cobalt and chromium (Col. 12 lines 13-23) with an outer layer that can comprise chromium nitride, with an interlayer. (Col. 12 , lines 54-68) Since there does not seem to be a difference in the product given by the applicant and the product given by Grab, then the process portions of applicants claims 12, 18-22 and 27, beginning with the surface of the body being exposed to a gas including nitrogen is considered to be a product-by – process limitation and “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.”, (*In re Thorpe*, 227 USPQ 964,966). Once the Examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious different between the claimed product and the prior art product (*In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983), MPEP 2113).

The recitation of the article being a medical device has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are

Art Unit: 1775

able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Hein (U.S. Pat. No. 6,905,773).

Consider claims 1, Hein teaches a metallic and molded plastic substrate with a coating of Chromium nitride. (Col. 4, lines 12-67)

The recitation of the article being a medical device has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 3, 7, 8, 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shetty (Pat. No. 5,308,412).

Art Unit: 1775

Consider claims 2, 3, 7, 8, 13 and 14, Shetty teaches that the layer of CrN is to have a thickness as low as .2 microns (2000 angstroms) to .5 microns (5000 angstroms (Table II)) as well as Shetty teaching that the layer is to be limited to a thickness of less than 100 microns, which is considered to mean that the coating only has to be less than 100 microns thick. (Col. 7 lines 55-60) Shetty does not teach the exact same proportions as recited in the instant claims.

However, one of ordinary skill in the art at the time the invention was made would have considered the invention to have been obvious because the compositional proportions taught by Shetty overlap the instantly claimed proportions and therefore are considered to establish a prima facie case of obviousness. It would have been obvious to one of ordinary skill in the art to select any portion of the disclosed ranges including the instantly claimed ranges from the ranges disclosed in the prior art reference, particularly in view of the fact that;

“The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages”, In re Peterson 65 USPQ2d 1379 (CAFC 2003).

Also, In re Geisler 43 USPQ2d 1365 (Fed. Cir. 1997); In re Woodruff, 16 USPQ2d 1934 (CCPA 1976); In re Malagari, 182 USPQ 549, 553 (CCPA 1974) and MPEP 2144.05.

Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uchiyama (U.S. Pat. No. 4,943,486) as applied above, and further in view of Shetty (Pat. No. 5,308,412).

Consider claims 16 and 17, Uchiyama teaches a coated article, with a metallic substrate containing cobalt group alloys and a outer layer of chromium nitride carbide with a metallic chromium layer placed between the substrate and the chromium nitride carbide layer. (Claim 1 and Col. 2 lines 45-65) However, Uchiyama does not specifically teach the use of ASTM-75. Shetty teaches a method of surface hardening a cobalt-chromium based implant device. Shetty also teaches that the substrate or base is made of ASTM F-75 and ASTM F-799, because these materials maintain their corrosion resistance and fatigue strength. (Col. 3 lines 55-70) It would have been obvious to a person of ordinary skill in the art at the time of the invention for Uchiyama to use a known member of the cobalt alloy group, such as ASTM-75 as taught by Shetty, which provides corrosion resistance and fatigue strength (Shetty Col. 2 lines 10-20).

Uchiyama discloses the claimed invention except for the specific use of ASTM-75. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use ASTM-75 (taught as a known cobalt alloy by Shetty, since it is a member of the cobalt group of alloys) for its corrosion resistance and fatigue strength, because it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious engineering choice. In re Leshin, 125 USPQ 416.

Additionally, since ASTM-F-75 is made up of 5-7% molybdenum, then the limitation of claim 16 by the applicant is considered to be met by Uchiyama.

Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kukino (U.S. Pat. No. 6,620,491).

Consider claim 2-4, Kukino teaches that CrN can be used as a hard coating layer with the outer most layer being a chromium nitride layer. However, Kukino teaches that the film thickness of the hard coated outer layer is preferably between 0.5 μ -10 μ m, but does not specifically teach that the hard coating of CrN in these thicknesses. However, one of ordinary skill in the art at the time the invention was made would have considered the invention to have been obvious because the compositional proportions taught by Kukino overlap the instantly claimed proportions and therefore are considered to establish a prima facie case of obviousness. It would have been obvious to one of ordinary skill in the art to select any portion of the disclosed ranges including the instantly claimed ranges from the ranges disclosed in the prior art reference, particularly in view of the fact that;

“The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages”, In re Peterson 65 USPQ2d 1379 (CAFC 2003).

Also, In re Geisler 43 USPQ2d 1365 (Fed. Cir. 1997); In re Woodruff, 16 USPQ2d 1934 (CCPA 1976); In re Malagari, 182 USPQ 549, 553 (CCPA 1974) and MPEP 2144.05.

Additionally, Kukino teaches an intermediate layer that has a thickness of at most 1 μ m and preferably at least 0.005 μ m, which is considered to teach that the intermediate layer (or transition layer) can be thinner or a depth less than the outer surface layer. (Col. 3 lines 20-28)

Response to Arguments

Applicant's arguments, filed 3/29/2007, with respect to 35 U.S.C. 112 (2) have been fully considered and are persuasive. The rejection of claims 6, 11 and 17 has been withdrawn in regard to 35 U.S.C. 112 (2).

Applicant's arguments, filed 3/29/2007, with respect to 35 U.S.C. 102 (b) with Shetty have been fully considered and are persuasive. The rejection of claims 4, 9 and 15 has been withdrawn in regard to 35 U.S.C. 102 (b).

In regard to Shetty's disclosure of CrN, the statement in claim one and through out the claims that the outer coating, "substantially comprises chromium nitride" is given no more limiting validity than stating that the outer layer comprising chromium nitride. Therefore, the transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Mars Inc. v. H.J. Heinz Co.*, 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004) ("like the term 'comprising,' the terms 'containing' and 'mixture' are open-ended.").< *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003) ("The transition 'comprising' in a method claim indicates that the claim is open-ended and allows for additional steps."); *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means

that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); *Moleculon Research Corp. v.*

CBS, Inc., 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts").

As for Shetty possibly teaching against the use of CrN as a coating layer, while Shetty may pick out some undesirable attributes of a CrN layer, Shetty teaches that such a layer can be added as a hard coating and is therefore considered to teach the use of CrN as a hard coating layer. As for the percentages of CrN in the outer layer coating, the term "substantially comprising" is considered to have the same meaning as "comprising."

As for the process claims of 12, 18-22, 27 and 29, since no product is shown to be distinctly different than any of the cited prior art, then no patentable distinction is going to be declared in the process sections of the product-by-process claims 12, 18-22, 27 and 29 because, "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.", (*In re Thorpe*, 227 USPQ 964,966). Once the Examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the

Art Unit: 1775

prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product (*In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983), MPEP 2113).


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gordon R. Baldwin whose telephone number is (571)272-5166. The examiner can normally be reached on M-F 7:45-5:15.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jennifer McNeil can be reached on 571-272-1540. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GRB


JENNIFER C. MCNEIL
SUPERVISORY PATENT EXAMINER
6/22/7